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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/500,991	02/15/2000	Frank Uhlmann	0652.2040000/REF	3282

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EXAMINER

FRONDA, CHRISTIAN L

ART UNIT

PAPER NUMBER

1652

DATE MAILED: 03/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/500,991

Applicant(s)

UHLMANN ET AL.

Examiner

Christian L. Fronda

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 December 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 36,37,40,41,43,44,46-49,58 and 59 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 36,37,40,41,43,44,46-49 and 58 is/are rejected.
- 7) ☒ Claim(s) 59 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 15 February 2000 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

1. Claims 36, 37, 40, 41, 43, 44, 46-49, 58, and 59 are under consideration in this Office Action.

Claim Rejections - 35 U.S.C. § 112, 1st Paragraph

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 36, 37, 40, 41, 43, 44, 46-49, 58 stand rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicants' arguments filed 12/20/2004, have been fully considered but they are not persuasive. Applicants' position is that the specification provides several separin substrates in addition to SEQ ID NO: 1, the specification provides guidance for generating fragments and variants, and the specification provides the sequence motif EXXR. The Examiner disagrees for the reasons of record as supplemented below.

Although the specification lists several separin substrates in addition to SEQ ID NO: 1, the specification, however, does not describe a substantial portion of an amino acid sequence that is common to all members of the claimed genus of separin substrates. The claims encompass a highly variant genus of substrates with widely differing structural, chemical, and physical characteristics. The genus is highly variable because a significant number of structural differences between genus members exists.

While the specification discloses a human SCC1 protein substrate consisting of the amino acid sequence of SEQ ID NO: 1, claims 46 and 47 also encompass fragments or variants thereof which have structural, chemical, and physical characteristics that are different from the disclosed protein substrate consisting of the amino acid sequence of SEQ ID NO: 1. The specification does not provide a written description for these fragments or variants of SEQ ID NO:1 which can be

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used in the claimed method.

While claims 46 and 58 recite the "human SCC1" substrate, the instant specification discloses a single "human SCC1" substrate consisting of SEQ ID NO: 1. Those sequences that are "human" are a subset of this genus of separin substrates. The specification fails to define those structural features of SEQ ID NO: 1 that are commonly possessed by members of the genus that distinguish them from other "non-human" polypeptides. Thus, one skilled in the art cannot visualize or recognize the identity of the members of the genus. As such, this single representative species does not adequately describe this subset according to its structure so that one of skill in the art can visualize and distinguish those amino acid sequences that are human, particularly in view of the larger genus that includes both human and non-human sequences.

The Court of Appeals for the Federal Circuit has recently held that a "written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definitions, such as the structure, formula [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials." *University of California v. Eli Lilly and Co.* 43 USPQ2d 1398 (Fed. Cir. 1997), quoting *Fiers v. Revel*, 984 F.2d 1164, 1171, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993) (bracketed material in original). To fully describe the genus of genetic materials, which is a chemical compound, applicants must (1) fully describe at least one species of the claimed genus sufficient to represent said genus whereby a skilled artisan, in view of the prior art, could predict the structure of other species encompassed by the claimed genus and (2) identify the common characteristics for the claimed molecules, e.g. structure, physical and/or chemical characteristics, functional characteristics when coupled with a known or disclosed correlation between function and structure, or a combination of these.

In view of the above considerations, applicants have failed to sufficiently describe the claimed invention, in such full, clear, concise, and exact terms that a skilled artisan would recognize Applicants were in possession of the claimed invention.

Claim Rejections - 35 U.S.C. § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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5. Claims 36, 37, 40, 41, 43, 44, and 48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brown et al. (reference AJ cited in PTO 1449 dated 08/03/2000) in view of Ciosk et al. (reference AM cited in PTO 1449 dated 08/03/2000).

Brown et al. teach a high-throughput fluorometric process for measuring protease activity comprising contacting a fluoregenic peptide labeled at one end with a UV/blue fluorophore and at the other end a quencher in the presence of an inhibitor test compound (see entire publication, especially **Discussion** section on pp. 155-157). Brown et al. does not teach the process steps of claims 36, 37, 40, 41, 43, 44, and 48.

Ciosk et al. teach a recombinant separin called Esp1p and its yeast substrate Scc1 (see entire publication, especially **Experimental Procedures** section on p. 1075).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the process of Brown et al. such that the separain and yeast substrate Scc1 taught by Ciosk et al. is used in the process taught by Brown et al., where the yeast substrate Scc1 is labeled at one end with a UV/blue fluorophore and at the other end a quencher. One of ordinary skill in the art at the time the invention was made would have been motivated to do this for the purposes of having a fast and simple process for identifying separase inhibitors.

No patentable weight is given to the preamble of process claims 36, 37, 40, 41, 43, 44, and 48 since it merely recites the purpose of these process claims. Thus, the process steps of the modified Brown et al. process stated above renders the claims obvious because these process steps are the same as the process steps of claims 36, 37, 40, 41, 43, 44, and 48. Because the process steps of the modified Brown et al. process stated above are the same as the process steps of these claims, then the modified Brown et al. process would inherently identify compounds that inhibit sister chromatic separation in eukaryotic cells.

Conclusion

6. No claims are allowed.

7. Claim 59 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any


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intervening claims.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christian L Fronda whose telephone number is (571)272-0929. The examiner can normally be reached Monday-Friday between 9:00AM - 5:00PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura N Achutamurthy can be reached on (571)272-0928. The fax phone number for the organization where this application or proceeding is assigned is (571)273-8300.

9. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

CLF


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